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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,337	08/06/2003	Valerie Niddam-Hildesheim	1662/604078	8108

26646 7590 12/28/2005

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ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

JOHNSEN, JASON H

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/635,337	Applicant(s) NIDDAM-HILDESHEIM ET AL.	
	Examiner Jason H. Johnsen	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,7-11,15,16,19-21,24-27,29,31,36,37 and 3335 is/are rejected.
- 7) ☐ Claim(s) 3-6,9,12-14,17,18,22,23,28,30,32 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/10/04,9/10/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 05/10/04 and 09/10/04 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Masumoto et al. (US 5,880,283).

MPEP 2112 states: “SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY.”

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

In this case, the “unknown property” is the particular crystalline form. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC.

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

Applicants are reminded that the PTO has no testing facilities. If applicants' reasoning were accepted, then any anticipation rejection of an old compound could always be overcome by tacking on some characteristic or property which the reference was silent on, regardless of whether the prior art material was any different from the claimed material. For example, if it did not happen to mention the color, one could patent an old compound just by adding “which is green” or “which is not indigo”. One could put in a limitation about density (e.g. “density is not 1.4”), melting point, “refractive index of 2.0”, solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Or one could add properties like or “does not explode on tapping” or “in the form of microneedles” or, as here, give the interplanar spacings.

Applicant's argument seems to be that so long as there is some difference in procedure, then the product is different. If this reasoning were correct, then gaining patents on old materials would be extremely simple. Applicants would just need to append some characteristic on which the prior art is

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silent (crystalline form, refractive index, density, color, average particle size, solubility in some obscure solvent, spectroscopic data, failure to explode when tapped, etc) and make sure that they used a slightly different method of manufacture.

With regard to these rejections, applicants state that a different method crystallization was employed than was used by applicants. This is of no real relevance, since most of the time, the same crystalline habit is obtained regardless of which method is employed, because most compounds are not polymorphic. Indeed, even among compounds that *are* polymorphic, it is common for several different methods to produce the same form, even if still other methods do not. In fact, in this case, applicants state that an entire category of solvents, any ester of acetic acid, will produce this form.

By the same token, even if the prior art method looked to be the same used by applicants, the examiner could not possibly present “technical reasoning” to deduce that it has these interplanar spacings. One cannot infer interplanar spacings from chemical techniques. Further, one cannot even deduce that it is the same crystalline form even if one ignores the numbers. It is well known that, sometimes, even small changes in procedure and conditions (such as the temperature employed, the speed of cooling (if cooling is used), the level of purity of the material, the concentration of the material in the solvent, the relative amounts of the two solvents (the solvent/anti-solvent ratio, when a solvent-antisolvent crystallization is being employed), the dryness of the solvent etc.) will produce a different crystalline form. Thus, neither differences in procedure nor similarities in procedure can give rise to a deduction that the crystalline form is different, or the same, respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention. These claims recite limitations that are not found in the text or body of the claims. References to figures or formulas that are not found outside of the claim set, either in the specification, or elsewhere, are not permitted, rendering these claims indefinite. In other words, there is insufficient antecedent basis for these limitations in the claims.

2. Claims 18, 28, 30, 32, and 34 are rejected under 35 U.S.C. 112, second paragraph, because claims that depend from an indefinite claim are also indefinite if they fail to obviate the reason the claim(s) from which they depend are rejected.

Claim Objections

1. Claims 9 and 18 are objected to for depending on a higher numbered claim. Dependent claims should depend from claims numbered before it in the claim set.

2. Claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34 are objected to for depending on a rejected base claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**.

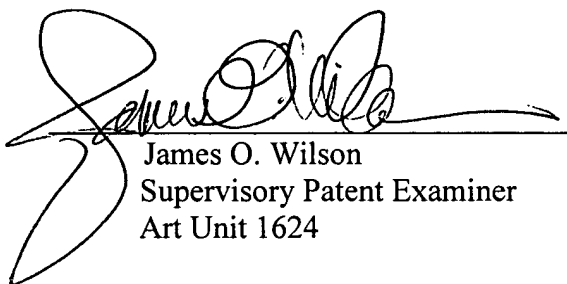
The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason H. Johnsen
Patent Examiner
Art Unit 1624



James O. Wilson
Supervisory Patent Examiner
Art Unit 1624